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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,351	03/19/2001	Sidney T. Smith	CRTS-5679 (1417A P 450)	3473

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EXAMINER
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PASCUA, JES F

ART UNIT	PAPER NUMBER
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3727

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/813,351	SMITH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jes F. Pascua	3727	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/7/06.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,6-8,12,14,15,17-19,22,23,29-31,36-49 and 51-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,6-8,12,14,15,17-19,22,23,29-31,36-38,43,44 and 51-56 is/are rejected.
- 7) ☒ Claim(s) 39-42 and 45-49 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's remarks filed 03/07/2006 indicate that an Affidavit of William S. Hurst under 37 C.F.R. 1.132 accompanied Applicant's response filed 10/21/2005. The Hurst affidavit was considered by the USPTO as an Artifact and therefore, the Hurst affidavit was not scanned and placed into the record by the USPTO. Consequently, the Examiner did not consider the Artifact and thus did not consider the Hurst affidavit. For the purpose of considering the Hurst affidavit, the finality of the rejection of the last Office action is withdrawn.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2, 6, 7, 8, 12, 14, 15, 17, 18, 19, 22, 30, 31, 52, 53, 54 and 55 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,988,422 to Vallot (previously cited). See Figs. 1 and 2.

It is brought to applicant's attention that the angle defined between the longitudinal edges 19, 19' and the tapered edges 17, 17', 18, 18' in Fig. 2 of Vallot is shown as being in the range from about 135.01° to about 138°, as claimed. Moreover, applicant's affidavit, filed 03/11/2005, admits that Vallot discloses an "angle range of

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120° -150° between the panel peripheral edge and the end segment tapered edge.”

See paragraph 6 of the 03/11/2005 affidavit. Having met applicant's claimed range of angles in claims 17 and 18, the end panels of Vallot are inherently capable of extending outwardly from the sleeve beyond an imaginary plane when in the unfolded position shown in Fig. 2.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 6, 7, 8, 12, 14, 15, 17, 18, 19, 22, 23, 30, 31, 52, 53, 54, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallot.

Vallot discloses the claimed invention, especially an angle range of 120° -150° between the panel peripheral edge and the end segment tapered edge, which overlaps applicant's claimed angle range of 135.01° to about 138° and specific angle 136°. However, Vallot does not disclose end panels extending outwardly beyond an imaginary plane at the ends of the sleeve as a result of an angle range of 135.01° to about 138° and specific angle 136°. Through routine experimentation, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an angle between the panel peripheral edge and the end segment tapered edge in Vallot with an angle range of 135.01° to about 138° or a specific angle 136°, in order to form

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the bag with end panels extending outwardly beyond an imaginary place at the ends of the sleeve. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

6. Claims 36, 37, 38, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallot '422.

Vallot '422 discloses the claimed invention, especially all of the materials used to construct the Vallot '422 container and its accessories being "capable of withstanding exposure to radiation and other known sterilization techniques." See column 3, lines 46-50. However, Vallot does not disclose the port closure (i.e. "stopper") in sterile communication with the port (i.e. "chimneys 8"). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stopper of Vallot '422 in sterile communication with the port of the container since it was known in the art to maintain the contents of bio-pharmaceutical containers in a sterile condition.

Regarding claims 43 and 44, the large diameter tube connector 10, small diameter tube connector 11 or 90° elbow connector 13 meet the structure of applicant's "vent closure" to the same degree as claimed.

Regarding claim 37, Vallot '422 discloses the claimed invention except for the communication member (i.e. a tube connecting to large diameter tube connector 10, small diameter tube connector 11 or 90° elbow connector 13) being about 6 ft. to about 30 ft. long. It would have been an obvious matter of design choice to use a 6 ft. to 30 ft.

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tube for the communication member of Vallot '422, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

7. Claims 29 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallot '422 and Sasaki et al.

Vallot '422 discloses the claimed device except for the top side of the container having a plurality of spaced-apart hanger connection locations. Sasaki et al. discloses that it is known in the art to provide a plurality of spaced-apart hanger connection locations 14. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the top side of the Vallot '422 container with the plurality of spaced-apart hanger connection locations of Sasaki et al., in order to permit the container to be suspended. Furthermore, the plurality of spaced-apart hanger connection locations 14 of Sasaki et al are shown as being positioned inward from an outer edge of the top side as claimed.

***Allowable Subject Matter***

8. Claims 39-42 and 45-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

9. Applicant's arguments filed 03/06/2006 have been fully considered but they are not persuasive.

Applicant's remark that Vallot fails to provide a single example within the claimed angle range of 135.01°-138° does not remove the fact that the range of angles taught by Vallot anticipate applicant's claims. "[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated' if one of them is in the prior art." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

The Smith affidavit, filed 10/21/2005 is identical to the Smith affidavit filed 03/11/2005. Smith affidavit has been considered, but not deemed sufficient to rebut the Examiner's *prima facie* case of obviousness based on overlapping ranges. The Smith affidavit fails to show that the particular angle range of 135.01° to about 138° and specific angle 136° are critical by showing that the claimed angle range and specific angle achieve unexpected results relative to the angle range disclosed by Vallot. In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Since applicant has failed to show evidence exists of unexpected results within the claimed narrow range of 135.01°-138°, the broad angle range of 120°-150° in Vallot meets the claimed narrow range with sufficient specificity.

The Smith affidavit admits that below a certain angle, large volume flexible containers are prone to undesirable rupturing and beyond a certain angle, the large

volume flexible containers exhibited undesirable wrinkling within a support container. Since applicant was aware of these two undesirable conditions, another person having ordinary skill in the art of large volume flexible containers would be aware these two undesirable conditions as well. Therefore, through routine experimentation within the claimed angle range of Vallot, a person having ordinary skill in the art would be able to arrive at an optimum range of angles that provide a large volume flexible container that does not rupture or wrinkle within the support container when filled. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The Hurst affidavit filed 10/21/2005 (and resubmitted on 03/07/2006) has been presented to support applicant's argument that Vallot fails to provide an example within the claimed range of 135.01°-138°. According to the Hurst affidavit, only four models of large volume fluid-filled flexible containers were prepared using finite element analysis. The four models appear to represent the high end and low end of the range of angles in Vallot and the high end and low end of the range of angles in applicant's claims. The Hurst affidavit goes to explain the results of each model (e.g. shape of bag and the amount of wrinkling). The affidavit comes to the conclusion that the high end and low end models of the Vallot range of angles produces a shape or wrinkles that are undesirable and the high end and low end of the claimed range of angles provides a usable container with minimal wrinkling. Paragraph 5 of the Hurst affidavit does not precisely discuss how much more a flexible container with a 120° angle is unsupported



compared to a flexible container with a range of  $135.01^{\circ}$  to about  $138^{\circ}$ . The Hurst affidavit also does not discuss the acceptable amount of the flexible container can be unsupported and how this acceptable amount was determined. Paragraph 6 of the Hurst affidavit does not precisely discuss how many more wrinkles occur in a flexible container with a  $150^{\circ}$  angle than a flexible container with a range of  $135.01^{\circ}$  to about  $138^{\circ}$ . The Hurst affidavit also does not discuss the acceptable amount of wrinkling a flexible container can have and how this acceptable amount was determined. The testing and results in the Hurst affidavit neither take into account, nor discuss, angles just outside the angle range of  $135.01^{\circ}$  to about  $138^{\circ}$ . The absence of such information in the affidavit does not convince the Examiner that the claimed range of  $135.01^{\circ}$  to about  $138^{\circ}$  yields an unexpected bag shape with minimal wrinkling.

Like the Smith affidavit, the Hurst affidavit shows that below a certain angle, large volume flexible containers are prone to undesirable rupturing and beyond a certain angle; the large volume flexible containers exhibited undesirable wrinkling within a support container. Since applicant was aware of these two undesirable conditions, another person having ordinary skill in the art of large volume flexible containers would be aware these two undesirable conditions as well. Therefore, through routine experimentation within the claimed angle range of Vallot, a person having ordinary skill in the art would be able to arrive at an optimum range of angles that provide a large volume flexible container that does not rupture or wrinkle within the support container when filled. "[W]here the general conditions of a claim are disclosed in the prior art, it is

not inventive to discover the optimum or workable ranges by routine experimentation.”  
In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In response to applicant's argument that Sasaki et al. is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Sasaki et al. discloses the necessity of providing a plurality of spaced-apart hanger connection locations within a flexible bag that is to be contained within a support container.

Applicant's argument that Vallot fails to adequately address the problem of full support within the support container and the problems associated with wrinkling is not indicative of unexpected results. “The failure of the prior art to mention a problem may be due to the fact that in practice the problem is not a serious one or that a large number of satisfactory solutions is readily apparent.” See *In re Gershon*, 372 F.2d 535, 152 USPQ 602 (CCPA 1967). “An allegation of solving an unsolved problem in the art is not evidence of non-obvious unless it is shown that widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem.” See *In re Allen*, 139 USPQ 492, 495 (CCPA 1963).

***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jes F. Pascua whose telephone number is 571-272-4546. The examiner can normally be reached on Mon.-Thurs..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nathan J. Newhouse can be reached on 571-272-4544. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jes F. Pascua  
Primary Examiner  
Art Unit 3727

JFP